

### **Remarks/Arguments**

Applicants have received and carefully reviewed the Office Action of the Examiner mailed June 8, 2010. Currently, claims 22-38, 42, 43, and 45-47 remain pending of which claims 34-38, 43, and 45-47 were previously withdrawn. Claims 22-33 and 42 have been rejected. Favorable consideration of the following remarks is respectfully requested.

### **Election/Restrictions**

Claims 34-38, 43, and 45-47 stand withdrawn with traverse.

### **Claim Rejections – 35 USC § 112**

Claims 22-33 and 42 were rejected under 35 U.S.C. 112, first paragraph, as failing to meet the written description requirement. Applicant respectfully traverses the rejection for the following reason. Claim 22 recites a preformed crosslinked gelatin sponge and a wetting agent having specified characteristics coated thereon. A coating process which results in articles of the claim is described in Example 2 found at pages 18 to 22. The sponges 2A to be coated are described at page 18, lines 25-27 which refers to a sponge preparation method described at page 14, lines 19-20 (1B) which refer in turn to page 13, line 16 to page 14, line 3 (1A) with the specific notation that the wetting agents of that preparation scheme are to be omitted. The preparation method makes reference to cross-linking with formalin. Reference is also made to U.S. Patent No. 2,465,357 (Correll) which provides additional information regarding the preparation of cross-linked gelatin sponges by the foaming process employed therein. The sponges of Example 2 are explicitly identified as cross-linked throughout the text at pages 18 to 22. Further, the Examiner's attention is directed to the definition at page 8, lines 1-9 which indicates that the term "gelatin composition" is broad enough to encompass components other than gelatin and a cross-linking agent:

"The term "cross-linked gelatin" refers to well known gelatin foams or sponges which are cross-linked with a conventional cross-linking agent such as formaldehyde as described in the art by Correll<sup>1-3</sup>. The term "cross-linked gelatin composition" refers to compositions comprising

cross-linked gelatin. Such compositions often include other components such as a medicament<sup>8-10</sup> or a second polymer such as collagen<sup>13</sup> and starch<sup>6</sup>.”

In addition, the text at page 13, line 28 to page 14, line 1 adequately describes the preforming of cubes of about 1.5-2.0 cm from central locations within the initially formed foam buns.

It should be apparent that a preformed cross-linked gelatin sponge, the gelatin composition 2A, which is subsequently treated with a wetting agent and a non-aqueous solvent is not the final sponge product. The coating step is broadly described at page 18, lines 13-18 and in greater detail at page 19, lines 1-22 where the solvent is identified as the non-aqueous isopropanol. The preformed sponge is described as a 2 x 2 x 0.6 cm piece of gelatin composition 2A which was previously described as produced by the process of 1A. The relevant text is:

“A 2.times.2.times.0.6 cm piece of Gelatin Composition 2A was placed into each vial and the vial inverted to soak the composition with the solution. This was repeated for each solution. Two contact/soak times were employed, 10 seconds and one minute.

The coated Gelatin Compositions 2A were then removed, drained of excess liquid and air dried overnight.” (Emphasis added.)

Applicant believes that the disclosure of Example 2 as a whole and the text at page 18, lines 5-22 adequately supported, directly and by reference to other portions of the text, the amendment. It is now believed that the clarification above of the references within the cited text should be adequate.

“Possession may be shown in many ways. For example, possession may be shown by describing an actual reduction to practice of the claimed invention. Possession may also be shown by a clear depiction of the invention in detailed drawings or in structural chemical formulas which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention.

A specification may describe an actual reduction to practice by showing that the inventor constructed an embodiment or performed a process that met all the limitations of the claim and determined that the invention would work for its intended purpose. *Cooper v. Goldfarb*, 154 F.3d 1321, 1327, 47 USPQ2d 1896, 1901 (Fed. Cir. 1998). See also *UMC Elecs. Co. v. United States*, 816 F.2d 647, 652, 2 USPQ2d 1465, 1468 (Fed. Cir. 1987)”

Applicant respectfully requests that the rejection of claims 22-23 and 42 be withdrawn.

### **Claim Rejections – 35 USC § 102**

Claims 22-33 and 42 were rejected under 35 U.S.C. 102(b) as anticipated by Pawelchak et al. (U.S. Patent No. 4,292,972), hereinafter Pawelchak. After careful review, Applicant must respectfully traverse this rejection.

*“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.”*

*Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). (See MPEP § 2131).*

Nowhere does Pawelchak appear to teach or suggest: “wherein the wetting agent is coated on at least a substantial portion of the surface of the preformed gelatin sponge by soaking the preformed gelatin sponge in a coating solution including the wetting agent and the non-aqueous solvent”, as recited in independent claim 22.

Instead, Pawelchak appears to teach foaming a composition which includes a surface tension modifier, such that the surface tension modifier is dispersed throughout the gelatin whether before or after cross-linking. In the passage at col. 4, lines 47-56, cited by the Examiner, Tween 60 and the related compounds are said to be added to enhance the quality of the foam produced by foaming the composition thus indicating that the composition is not yet cross-linked when the surface tension modifier is added prior to foaming. Further, the composition at that stage is aqueous and does not appear to include a non-aqueous solvent.

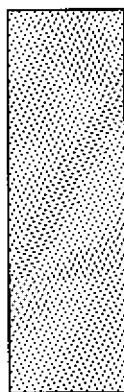
The Examiner appears to be asserting that the composition is anticipated because it contains similar components without properly taking into account that the materials of Pawelchak are not arranged as required by the claim.

“The identical invention must be shown in as complete detail as is contained in the ... claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test,

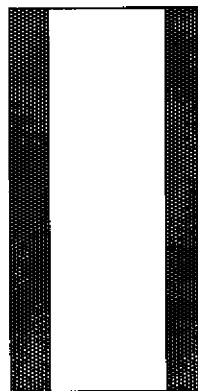
i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990) (MPEP 2131)

The surface tension modifier of Pawelchak appears to be dispersed throughout the material of the sponge by virtue of being present in the aqueous system prior to foaming and/or crosslinking. While the specific material cited, Tween 60, is soluble in certain non-aqueous solvents, that property does not appear to be utilized in preparing the uncross-linked precursor foams of Pawelchak nor does it appear to contribute to decreased hydration time as recited in claim 22. Although the same material appears to be present, it occupies a different position within the composition and thus would not be expected to contribute to the hydration of the sponge in the same manner and at the same rate for at least the reason that the Tween 60 appears to be separated from the hydrating water with which it might interact by significant amounts of unhydrated gelatin. By contrast, the Tween 60 or other wetting agent of the invention is essentially entirely present on the surface of the sponge where it is more or less immediately available to act as a wetting agent.

In the sponges of the invention, the wetting agent is coated on at least a substantial portion of the surface of the foam. As illustrated in the schematic sketch below, the surface tension modifier of Pawelchak is dispersed dilutely throughout the material comprising the struts of the foam cells while in the struts of the foam cells of the pending claims, the wetting agent is concentrated and confined to a coating layer on the surface of the strut with little if any wetting agent within the cross-linked gelatin for the reason that the cross-linked gelatin substrate is not significantly swollen by the non-aqueous solvent employed to provide the coating. Further, the ability to use a non-aqueous solvent for the coating application avoids collapse of the foam during the coating process.



Pawelchak



Pending claim 22

As illustrated in the experimental section of the pending application, the wetting agent Tween 60, specifically cited in the disclosure of Pawelchak, causes premature foam collapse (Table 5) when incorporated directly into the foaming composition under conditions taught by the pending application; however when coated onto the surface of a preformed sponge, deposition from a non-aqueous solvent does not significantly collapse the preformed and crosslinked foam and provides the benefit of reducing hydration time from 6 minutes to 24-35 seconds – a hydration time reduction of 90-93% with a wetting agent which was not otherwise usable in the sponge producing process of Correll. Other disclosed wetting agents which are available for use by virtue of their solubility characteristics are capable of greater reductions of wetting times without incurring reduced foam stability.

While some embodiments of Pawelchak may utilize similar materials in producing hydratable sponges, the cited Tween 60 is only added to the precursor to a foam which may subsequently lyophilized and/or cross-linked. Thus Pawelchak does not appear to disclose a cross-linked foam with a coating of a wetting agent on the surface thereof, wherein said wetting agent is soluble in a non-aqueous solvent.

The uniformly dispersed surface tension modifier of Pawelchak, which appears to be introduced prior to the production of a (foamed) sponge, does not appear to anticipate *each and every element as set forth in the claim*, and Applicants respectfully request that the rejections be withdrawn.

Additionally, for similar reasons as well as others, claims 23-33 and 42, which depend from claim 22, and include significant additional limitations, are believed to be

not anticipated by Pawelchak and Applicants respectfully request that the rejections be withdrawn.

### **Claim Rejections – 35 USC § 103**

Claim 26 was rejected under 35 U.S.C. 103(a) as being unpatentable over Pawelchak in view of Yasushi et al. (JP 02-182259), hereinafter Yasushi. After careful review, Applicant must respectfully traverse this rejection.

“All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). (MPEP § 2143.03). As discussed previously, nowhere does Pawelchak appear to disclose: “wherein the wetting agent is coated on at least a substantial portion of the surface of the preformed gelatin sponge by soaking the preformed gelatin sponge in a coating solution including the wetting agent and the non-aqueous solvent”, as recited in independent claim 22.

As stated in the cited Abstract of Yasushi, the surfactant of Yasushi is added to a precursor solution to the foam which is then foamed and freeze-dried prior to eventual crosslinking. Thus the disclosure of Yasushi parallels that of Pawelchak and also does not appear to disclose a preformed cross-linked sponge having a coating of a wetting agent having the property of being soluble in a non-aqueous solvent on the surface thereof. As discussed above, the mere presence of a dispersed phase within the gelatin sponge does not appear to teach or disclose a coating on the surface of a preformed and cross-linked sponge as would be required to teach all the claim limitations of claim 22, as is required to establish a *prima facie* case of obviousness.

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). (MPEP 2143.03)

Accordingly, claim 26, which depend from nonobvious independent claim 22, also is believed to be nonobvious and Applicants respectfully request that the rejection be withdrawn.

Claim 31 was rejected under 35 U.S.C. 103(a) as being unpatentable over Pawelchak in view of EP 5568 334 ('334). It is believed that the reference in question is intended to be Song et al. (EP 0 568 334), hereinafter Song. After careful review, Applicant must respectfully traverse this rejection.

Song was relied upon solely for the teaching of inclusion of growth factor in wound dressing as claimed in claim 31. That limitation does not appear in independent claim 22 and thus Song does not appear to overcome the deficiencies of Pawelchak as applied to independent claim 22.

Accordingly, claim 26, which depends from nonobvious independent claim 22, also is believed to be nonobvious and Applicants respectfully request that the rejection be withdrawn.

With regard to the Response to Arguments, there appears to be some confusion regarding elements disclosed by Pawelchak and when within the process disclosed by Pawelchak those elements may be characterized as indicated by the Examiner. More particularly, the rejection does not appear to appreciate the structural differences between the articles disclosed by Pawelchak and the structure associated with the claimed articles. Said structural differences result in different performance characteristics for compositionally similar materials. The Examiner does not appear to have asserted that the articles are structurally similar or that they have similar performance characteristics. Contrary to the Examiner's unsupported statement, the reference process of Pawelchak does not appear to provide a gelatin sponge coated with wetting agent, but rather appears to provide a gelatin sponge with a surface tension modifier dispersed within the gelatin phase of the sponge.

As noted above, incorporation of a surface tension modifier into a foamable composition indicates that the material has introduced prior to the formation of the foamed article or sponge and thus that the modifier will be dispersed throughout the resulting foam rather than present as a coating thereon. The foams of Pawelchak do not become preformed gelatin sponges until after the foaming process is complete and segments have been cut from the resulting bun or sheet. The cited surface tension modifier, Tween 60, is present as a foam stabilizer and thus is necessarily present while the foam is formed and is not therefore present as a coating applied to the preformed

cross-linked sponge as recited in the pending claim.

Further, a crosslinked gelatin would not generally be understood by one of ordinary skill in the art to be capable of being foamed and the disclosure of Pawelchak is consistent with that understanding. Cross-linking appears to be introduced only after the foaming process and optionally after freeze-drying. Again, this is consistent with the disclosure of Pawelchak that the surface tension modifier is introduced prior to the presence of a cross-linked preformed sponge.

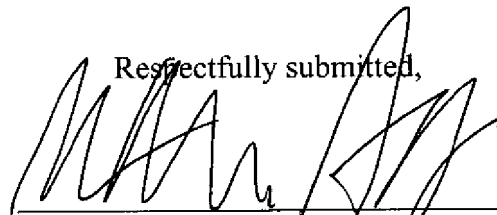
The article of Pawelchak is structurally distinct from the article of pending claim 22 by virtue of the surface tension modifier being dispersed within the gelatin of the gelatin sponge while in the article of claim 22 the wetting agent is present as a coating on the surface of the sponge. In Pawelchak the surface tension modifier is incorporated prior to the existence of a preformed cross-linked gelatin sponge and thus does not appear to be capable of forming a coating on the sponge.

Further, the appears to be nothing in the disclosure of Pawelchak which indicates that the sponges of Pawelchak exhibit the claimed enhanced hydration rates which are believed to necessitate the delivery system of withdrawn claims 43 and 45-47.

In view of the foregoing, all pending claims are believed to be in condition for allowance. Further examination, reconsideration, and withdrawal of the rejections are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

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Respectfully submitted,



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